

WHAT IS CLAIMED IS:

- 1 1. A body fluid sampling system for use on a tissue site, the system
2 comprising:
 - 3 a cartridge;
 - 4 a penetrating member driver;
 - 5 a plurality of penetrating members arranged in a radial configuration on
6 the cartridge wherein sharpened distal tips of the penetrating members point radially
7 outward;
 - 8 wherein an active one of said penetrating members may be operatively
9 coupled to said penetrating member driver, said penetrating member driver moving said
10 active one along a path out of a housing having a penetrating member exit, into said tissue
11 site, stopping in said tissue site, and withdrawing out of said tissue site; and
 - 12 a plurality of analyte detecting members, wherein at least one of said
13 analyte detecting members is positioned to receive fluid from a wound created by said
14 active one of said penetrating members, wherein said detecting members are not pierced
15 by the active one of the penetrating members.
 - 1 2. A system as in claim 1 wherein at least one of said detecting
2 members is mounted about a penetrating member exit.
 - 1 3. A system as in claim 1 wherein said detecting member is not
2 pierced by the penetrating member and is within 2 mm of a front end of the housing.
 - 1 4. A system as in claim 1 wherein said cartridge has a plurality of
2 penetrating member exits, and wherein at least one of said detecting members is mounted
3 about each of said penetrating member exits.
 - 1 5. A system as in claim 1 wherein said analyte detecting members
2 comprise test strips.
 - 1 6. A system as in claim 1 wherein said analyte detecting members are
2 housed in a second cartridge.

1 7. A system as in claim 6 wherein the second cartridge is integrated
2 with the cartridge housing the penetrating members.

1 8. A system as in claim 6 wherein the second cartridge may rotate
2 relative to the penetrating member driver.

1 9. A system as in claim 1 wherein detecting members are mounted in
2 a radial configuration on said cartridge.

1 10. A system as in claim 1 wherein said penetrating member driver
2 comprises a spring based launching device.

1 11. A system as in claim 1 wherein said analyte detecting member
2 comprises a test strip individually movable relative to said housing.

1 12. A system as in claim 1 wherein said detecting member is
2 configured to determine a concentration of an analyte in the fluid using a sample of less
3 than 1 μ l of the fluid.

1 13. A system as in claim 1 further comprising a penetrating member
2 sensor positioned to monitor a penetrating member coupled to said penetrating member
3 driver, the penetrating member sensor configured to provide information relative to a
4 depth of penetration of a penetrating member through a skin surface.

1 14. The system of claim 13, wherein the depth of penetration is about
2 100 to 2500 microns.

1 15. The system of claim 13, wherein the depth of penetration is 500 to
2 750 microns.

1 16. The system of claim 13, wherein the depth of penetration is no
2 more than about 1000 microns beyond a stratum corneum thickness of a skin surface.

1 17. The system of claim 13, wherein the depth of penetration is no
2 more than about 500 microns beyond a stratum corneum thickness of a skin surface.

1 18. The system of claim 13, wherein the penetrating member sensor is
2 further configured to provide an indication of velocity of a penetrating member.

1 19. The system of claim 1, wherein one of said analyte detecting
2 members is movable outward towards said wound to more easily engage said fluid.

1 20. The system of claim 1, wherein said analyte detecting members are
2 individually actuatable to extend outward from said housing.

1 21. The system of claim 1, wherein the driver is selected from one of
2 the following: a voice coil, a rotary voice coil, a solenoid, a motor and gear box, a
3 nanomuscle, or a combination of any of the above.

1 22. The system of claim 13, wherein the penetrating member sensor is
2 coupled to a processor with control instructions for the penetrating member driver.

1 23. The system of claim 22, wherein the processor includes a memory
2 for storage and retrieval of a set of penetrating member profiles utilized with the
3 penetrating member driver.

1 24. The system of claim 22, wherein the processor is utilized to
2 monitor position and speed of a penetrating member as the penetrating member moves in
3 a first direction.

1 25. The system of claim 22, wherein the processor is utilized to adjust
2 an application of force to a penetrating member to achieve a desired speed of the
3 penetrating member.

1 26. The system of claim 22, wherein the processor is utilized to adjust
2 an application of force to a penetrating member when the penetrating member contacts a
3 target tissue so that the penetrating member penetrates the target tissue so that the
4 penetrating member penetrates the target tissue within a desired range of speed.

1 27. The system of claim 22, wherein the processor is utilized to
2 monitor position and speed of a penetrating member as the penetrating member moves in
3 the first direction toward a target tissue, wherein the application of a launching force to
4 the penetrating member is controlled based on position and speed of the penetrating
5 member.

1 28. The system of claim 27, wherein the processor is utilized to control
2 a withdraw force to the penetrating member so that the penetrating member moves in a
3 second direction away from the target tissue.

1 29. The system of claim 28, wherein in the first direction the
2 penetrating member moves toward the target tissue at a speed that is different than a
3 speed at which the penetrating member moves away from the target tissue.

1 30. The system of claim 28, wherein in the first direction the
2 penetrating member moves toward the target tissue at a speed that is greater than a speed
3 at which the penetrating member moves away from the target tissue.

1 31. The system of claim 27, wherein a speed of a penetrating member
2 in the first direction is the range of about 2.0 to 10.0 m/sec.

1 32. The system of claim 27, wherein a speed of a penetrating member
2 in the first direction is the range of 1.0 to 10.0 m/sec.

1 33. The system of claim 27, wherein a speed of a penetrating member
2 in the first direction is the range of 3.0 to 8.0 m/sec.

1 34. The system of claim 27, wherein a dwell time of the penetrating
2 member in the target tissue below a skin surface is in the range of 1 microsecond to 2
3 seconds.

1 35. The system of claim 1, wherein a dwell time of the penetrating
2 member in the target tissue below a skin surface is in the range of 500 milliseconds to 1.5
3 second.

1 36. The system of claim 1, wherein a dwell time of the penetrating
2 member in the target tissue below a skin surface is in the range of 100 milliseconds to 1
3 second.

1 37. The system of claim 28, wherein the average velocity of the
2 penetrating member during a tissue penetration stroke in the first direction is about 100 to
3 about 1000 times greater than the average velocity of the penetrating member during a
4 withdrawal stroke in a second direction.

1 38. The system of claim 13, wherein the penetrating member sensor is
2 selected from one of the following: a capacitive incremental encoder, an incremental
3 encoder, an optical encoder, or interference encoder.

1 39. The system of claim 1 further comprising a plurality of analyte
2 detecting members positioned to receive body fluid from said wound.

1 40. The system of claim 1, further comprising:
2 a sample chamber with an opening for transport of a body fluid into the
3 sample chamber, the sample chamber being sized to receive no more than about 1.0 µl of
4 the body fluid.

1 41. The system of claim 1, further comprising:
2 a sample chamber with an opening for transport of a body fluid into the
3 sample chamber, the sample chamber being sized to receive no more than about 0.75 µl
4 of the body fluid.

1 42. The system of claim 1, further comprising:
2 a sample chamber with an opening for transport of a body fluid into the
3 sample chamber, the sample chamber being sized to receive no more than about 0.5 µl of
4 the body fluid.

1 43. The system of claim 1, further comprising:
2 a sample chamber with an opening for transport of a body fluid into the
3 sample chamber, the sample chamber being sized to receive no more than about 0.25 µl of
4 the body fluid.

1 44. The system of claim 1, further comprising:
2 a sample chamber with an opening for transport of a body fluid into the
3 sample chamber, the sample chamber being sized to receive no more than about 0.1 µl of
4 the body fluid.

1 45. The system of claim 1, further comprising:
2 an analyte detecting member coupled to a sample chamber, the analyte
3 detecting member being configured to determine a concentration of an analyte in a body

4 fluid using a sample that does not exceed a volume of about 1 μ l of a body fluid disposed
5 in the sample chamber.

1 46. The system of claim 1, further comprising:
2 an analyte detecting member coupled to a sample chamber, the analyte
3 detecting member being configured to determine a concentration of an analyte in a body
4 fluid using a sample that does not exceed a volume of about 0.75 μ l of a body fluid
5 disposed in the sample chamber.

1 47. The system of claim 1, further comprising:
2 an analyte detecting member coupled to a sample chamber, the analyte
3 detecting member being configured to determine a concentration of an analyte in a body
4 fluid using a sample that does not exceed a volume of about 0.5 μ l of a body fluid
5 disposed in the sample chamber.

1 48. The system of claim 1, further comprising:
2 an analyte detecting member coupled to a sample chamber, the analyte
3 detecting member being configured to determine a concentration of an analyte in a body
4 fluid using a sample that does not exceed a volume of about 0.25 μ l of a body fluid
5 disposed in the sample chamber.

1 49. The system of claim 1, further comprising:
2 an analyte detecting member coupled to a sample chamber, the analyte
3 detecting member being configured to determine a concentration of an analyte in a body
4 fluid using a sample that does not exceed a volume of about 0.1 μ l of a body fluid
5 disposed in the sample chamber.

1 50. The system of claim 1, further comprising:
2 a tissue stabilizer device coupled to the housing.

1 51. The system of claim 50, wherein the tissue stabilizer device applies
2 a vacuum to a target tissue.

1 52. The system of claim 50, wherein the tissue stabilizer device is
2 configured to apply a force to a target tissue and cause the target tissue to press in an
3 inward direction relative to the housing member.

1 53. The system of claim 1, further comprising:
2 a seal formed by a fracturable material between the penetrating member
3 and the cartridge, the seal being positioned at least one of a distal port or a proximal port
4 of the cartridge.

1 54. The system of claim 50, further comprising
2 a second fracturable seal located at least one of the distal port or proximal
3 port of cartridge.

1 55. The system of claim 50, further comprising
2 at least three fracturable seal between the penetrating member and the
3 cartridge.

1 56. The system of claim 1 further comprising a vacuum source to
2 provide a low pressure environment to draw fluid from a wound created by the
3 penetrating member in the tissue.

1 57. The system of claim 1, wherein each penetrating member each
2 penetrating members is an elongate member without molded attachments.

1 58. The system of claim 1, wherein each penetrating member each
2 penetrating members comprises a needle having a lumen therein.

1 59. The system of claim 1, wherein each penetrating member each
2 penetrating members comprises a microneedle having a lumen therein.

1 60. The system of claim 1 further comprising a resilient member
2 coupled to said penetrating member, said penetrating member driver aligned to move said
3 resilient member which in turn moves the penetrating member.

1 61. The system of claim 1 wherein:
2 the penetrating member comprises a spring based device and at one of the
3 following: a motor and gear box, a nanomuscle, pneumatic device, a liquid magnetic coil
4 actuation device, a stepper motor, a micro-clutch device, and an inductive motor.

1 62. The system of claim 1 wherein the penetrating member exit is
2 configured to be positioned against the tissue when the penetrating member contacts the
3 tissue.

1 63. A body fluid sampling system for use on a tissue site, the system
2 comprising:

3 a cartridge;

4 a penetrating member driver;

5 a plurality of penetrating members, each having a proximal end, an
6 elongate portion, and a sharpened distal end, said members arranged in a radial
7 configuration on the cartridge wherein sharpened distal tips of the penetrating members
8 point radially outward;

9 wherein an active one of said penetrating members may be operatively
10 coupled to said penetrating member driver, said penetrating member driver moving said
11 active one along a path out of a housing having a penetrating member exit, into said tissue
12 site, stopping in said tissue site, and withdrawing out of said tissue site; and

13 a plurality of analyte detecting members, wherein at least one of said
14 analyte detecting members is positioned to receive fluid from a wound created by said
15 active one of said penetrating members;

16 wherein said unused analyte detecting members are arranged in a stack.

17 said penetrating member driver configured to be controlled to follow a
18 velocity trajectory into the tissue and out of said tissue, wherein said velocity into said
19 tissue is at an average speed greater than an average speed of the penetrating member on
20 the withdrawal.

1 64. A body fluid sampling system for use on a tissue site, the system
2 comprising:

3 a cartridge;

4 a penetrating member driver;

5 a plurality of penetrating members arranged in a radial configuration on
6 the cartridge wherein sharpened distal tips of the penetrating members point radially
7 outward;

8 wherein an active one of said penetrating members may be operatively
9 coupled to said penetrating member driver, said penetrating member driver moving said

10 active one along a path out of a housing having a penetrating member exit, into said tissue
11 site, stopping in said tissue site, and withdrawing out of said tissue site; and
12 a plurality of analyte detecting members, wherein at least one of said
13 analyte detecting members is positioned to receive fluid from a wound created by said
14 active one of said penetrating members, wherein said detecting members are not pierced
15 by the active one of the penetrating members;
16 a position sensor positioned to provide an indication of a position of the
17 penetrating member during actuation.

1 65. A body fluid sampling system for use on a tissue site, the system
2 comprising:
3 a cartridge;
4 a penetrating member driver;
5 a plurality of penetrating members arranged in a radial configuration on
6 the cartridge wherein sharpened distal tips of the penetrating members point radially
7 outward;
8 wherein an active one of said penetrating members may be operatively
9 coupled to said penetrating member driver, said penetrating member driver moving said
10 active one along a path out of a housing having a penetrating member exit, into said tissue
11 site, stopping in said tissue site, and withdrawing out of said tissue site; and
12 a plurality of analyte detecting members, wherein at least one of said
13 analyte detecting members is positioned to receive fluid from a wound created by said
14 active one of said penetrating members, wherein said detecting members are not pierced
15 by the active one of the penetrating members;
16 a coupler on said penetrating member driver configured to engage at least
17 a portion of said elongate portion of the penetrating member and drive said member along
18 a path into a tissue site and withdrawn from a tissue site.

1 66. A body fluid sampling system for use on a tissue site, the system
2 comprising:
3 a cartridge;
4 a penetrating member driver;

5 a plurality of penetrating members arranged in a radial configuration on
6 the cartridge wherein sharpened distal tips of the penetrating members point radially
7 outward;

8 wherein an active one of said penetrating members may be operatively
9 coupled to said penetrating member driver, said penetrating member driver moving said
10 active one along a path out of a housing having a penetrating member exit, into said tissue
11 site, stopping in said tissue site, and withdrawing out of said tissue site; and

12 a plurality of analyte detecting members, wherein at least one of said
13 analyte detecting members is positioned to receive fluid from a wound created by said
14 active one of said penetrating members, wherein said detecting members are not pierced
15 by the active one of the penetrating members;

16 a sterility enclosure covering at least a tip of said penetrating member, said
17 sterility enclosure removed from said penetrating member prior to actuation of the
18 member and positioned so that the penetrating member will not contact said enclosure
19 during actuation.

1 67. A body fluid sampling system for use on a tissue site, the system
2 comprising:

3 a cartridge;

4 a penetrating member driver;

5 a plurality of penetrating members arranged in a radial configuration on
6 the cartridge wherein sharpened distal tips of the penetrating members point radially
7 outward;

8 wherein an active one of said penetrating members may be operatively
9 coupled to said penetrating member driver, said penetrating member driver moving said
10 active one along a path out of a housing having a penetrating member exit, into said tissue
11 site, stopping in said tissue site, and withdrawing out of said tissue site; and

12 a plurality of analyte detecting members, wherein at least one of said
13 analyte detecting members is positioned to receive fluid from a wound created by said
14 active one of said penetrating members, wherein said detecting members are not pierced
15 by the active one of the penetrating members;

16 a user interface for transmitting at least one input between a user.